

**DETAILED ACTION**

***Specification***

1. The disclosure is objected to because of the following informalities: The brief description of drawings on pp. 23 and 24 needs listing for each and every figure listed. Listings such as “1a-e” or “3a-d” do not list each and every figure. For example, the examiner recommends the applicant change “1a-e” on p. 23, l. 9 to --1a, 1b, 1c, 1d, and 1e-- to remedy this objection. Similar changes should be made to the other listed figures as well.

Appropriate correction is required.

***Claim Objections***

2. Claim 37 is objected to under 37 CFR 1.75(c) as being in improper form because it depends simultaneously for both claim 30 and claim 1. Dependent claims can only depend from a multiple of earlier claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 37 not been further treated on the merits.
3. The examiner also notes that claim status identifiers for claims 13-38 are improper as “Secondly Amended” and “Previously Amended in PCT Application” are not recognized status identifiers. These should be changed in the next response to this office action.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claim 1, it is unclear of the metes and bound of the limitation “the device having no outgoing lines” because even the present invention would read on a device having outgoing lines giving the claim language its broadest reasonable interpretation. For example, the filaments 15 in fig. 1e would read on outgoing lines. The outer surface of the elements 15 in fig. 4b and 4c as well as the bulb of electrical material shown in fig. 6c and 6d would also read in an outgoing line giving the claim language its broadest reasonable interpretation. The use of a negative limitation is only permissible when it is clear that all possible interpretations of the negative limitation read free of the present invention, which is not the case here.

7. In claims 4, 5, 7, 11, 13, 15, 16, 22, and 33, the use of “in particular” or “particularly” renders these claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8. In claims 36 and 38, there is no antecedent basis for “the electrochemical detection”. It would appear that these claims should further depend from either claim 31 or 32 and not claim 30. For the purpose of examination, the examiner will presume that claims 36 and 38 depend from either claim 31 or 32, but clarification and correction is required.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-8, 11-14, 19, 20, 30, 31, 33, 35, 36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/75151 (hereafter "WO '151") in view of any of Leader et al (USP 5,858,452), Pfab et al (USP 5,018,527), or DE 198 42 735 A1 (hereafter "DE '735"). For WO '151, the examiner is relying on the English language disclosure of Hoffman et al (US 2003/0226768 A1). All text citations for WO '151 will refer to the location of the text in Hoffman.

13. WO '151 discloses a device for detecting a multiplicity of different analytes in a liquid having a multiplicity of different electrodes (101, 102) that are insulated from one another and are arranged on a first side of an electrically nonconductive plate 103 (paragraph 0060). Because plate 103 is not disclosed as being porous or otherwise permeable to liquid, plate 103 is either inherently impermeable to liquid or it would have been obvious to make plate 103 impermeable to liquid. The plate is flat and inherently having a first and second side. The electrodes (101, 102) having a analyte specific molecule (106, 107) having differing specificity by virtue of having a specific affinity for the analyte (paragraph 0094) and this plate would meet the broadest reasonable interpretation of a chip. WO '151 does not explicitly disclose having the electrical contact be connected and conducted out of a second side of a plate by means of electrical conductors extending through the plate, although WO '151 does show pictorially the use of electrical contacts (104, 105) extending through the plate. However, it is well known in the electrochemical sensor art that the electrical contacts for electrodes lying on one face of a plate can be made through the plate via a second face of the plate. This is demonstrated by Leader which shows a hole 702 that is filled with electrical material extending through a plate 405 for making the electrical contact to the electrode, which provides a sensor having a short electrical path to the electrodes where the electrical path is not contaminated by sample exposure, thereby providing improved sensor response. See fig. 8 and 9; col. 4, ll. 1-55. Pfab also teaches that electrical connection between electrodes on one face of a chip can be made on the other face of the chip via holes through the chip, and such a structure provides a means for providing numerous insulated electrical contacts (termed "shunts" in Pfab) in a small area. See fig. 8 and col. 4, ll. 18-34. DE '735 also discloses in an alternate electrochemical sensor that electrical

connections to electrodes can be made on the opposite surface of the chip thereby obviating the need for electrical leads on the same face of the chip as the electrodes. See fig. 3. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize electrical contacts that extend through the chip to a second face of the chip as suggested by any of Leader, Pfab, or DE '735 for the device of WO '151 both because it was well established in the art to have the sensor electrical connections extend through the substrate holding the electrodes and because it provides a short electrical path (Leader), provides a connection not susceptible to contamination (Leader), and allows a high density of electrodes for a given surface area of a chip (Pfab).

14. With respect to forming the electrodes together with the electrical conductors, the determination of patentability for the claim is based on the product itself. The process from which it was made is the same as or obvious over the process utilized by the above references (see *In re Thorpe*, 777 F.2d 695, 698).

15. With respect to the composition of the coating, WO '151 teaches the use of nucleic acid capture molecules covalently bound to the electrodes. See paragraphs 0069-0071.

16. With respect to the presence of perforations, each of Leader, Pfab, and DE '735 utilized perforations for its electrical conductors. With respect to the use of a taper, it would have been an obvious matter of engineering choice to utilize a taper, since such a modification would have involved a mere change in the shape or form of a component. A change in shape or form is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 149 USPQ 47 (CCPA 1976).

17. With respect to the device being arranged on the bottom of a microfluid chamber, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. How the device is to be further utilized does not further define the actual device itself.

18. With respect to the number of electrodes to be utilized, WO '151 shows the use of at least 16 electrodes for the device.

19. With respect to the electrode being formed from particles, the determination of patentability for the claim is based on the product itself. The process from which it was made is the same as or obvious over the process utilized by the above references (see *In re Thorpe*, 777 F.2d 695, 698).

20. With respect to the process of producing the device, Leader teaches providing a plate with perforations, applying a paste of curable electrode material to a first side and pressing the electrode material into the perforations. See col. 10, ll. 21-58 and col. 12, ll. 3-9. With respect to removing electrode material between the perforations, common sense would dictate that any excess electrode material left between the electrodes (and hence between the perforations as well) that happens to form during the deposition step should be removed to avoid metallic elements on the plate surface that can short out the measuring electrodes during use. For example, the use of a cleaning step to remove impurities from the front face of the chip after the deposition steps would read on the defined "removing" of the claims.

21. With respect to the use of a mask for introducing the material into the holes, Leader already disclosed that masks could be utilized to fill each of the holes of the device. See col. 9, l. 54 - col. 10, l. 20.

22. With respect to an analyte liquid being brought into contact with the electrodes, see WO '151 paragraphs 0123-0125.
23. With respect to the use of a redox reaction, see WO '151 paragraph 0216.
24. With respect to claims 36 and 38, the examiner believes that these claims should depend from either claim 31 or 32 (see 112 rejection above). Furthermore, these claims would only further limit claim 31 when electrochemically is chosen from the Markush group of claim 31. Because claims 36 and 38 do not actually require electrochemically be chosen from the groupings of claim 31, claims 36 and 38 do not further limit claim 31 when electrically is chosen.
25. Claims 9, 10, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '151 in view of any of Leader, Pfab, or DE '735 as applied to claims 1 and 30 above, and further in view of Cozzette et al (USP 5,063,081).
26. The references set forth all the limitations of the claims, but did not explicitly recite the use of a semipermeable covering of the electrode. Cozzette teaches the use of semipermeable films over sensing electrodes as a barrier against interferents and to allow the transport of only analyte of interest. See col. 13, ll. 54-62. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Cozzette for the device and use of the device of WO '151 in view of any of Leader, Pfab, or DE '735 so as to minimize the influence of interferents as well as make the various electrodes of WO '151 selective to only analytes of interest.

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27. With respect to the use of different permeabilities, because the various electrodes of WO '151 are sensitivity to different analytes (paragraph 0094), the use of different semipermeable membranes for these different analytes would have required only routine skill in the art.

28. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '151 in view of any of Leader, Pfab, or DE '735 as applied to claim 1 above, and further in view of Mitchell et al (USP 4,713,347).

29. The references set forth all the limitations of the claims, but did not explicitly recite the use of a non-metallic conductor. Mitchell teaches that non-metallic carbon finds utility for sensor electrodes owing to its non-specific catalytic activity. See col. 42, ll. 15-18. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Mitchell for the device of WO '151 in view of any of Leader, Pfab, or DE '735 in order to avoid the use of materials that might have specific catalytic activity for another analyte or interferent.

30. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '151 in view of any of Leader, Pfab, or DE '735 as applied to claim 1 above, and further in view of Hashimoto et al (USP 6,818,109).

31. The references set forth all the limitations of the claim, and WO '151 further disclosed the use of a reference electrode, but did not explicitly disclose the use of a counter electrode as well. Hashimoto teaches the addition of a counter electrode to the nucleic acid detection sensor, which improves the sensor response. See col. 2, ll. 10-20 and col. 4, ll. 6-33. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a counter electrode for the device of WO '151 so that the device so as to improve the sensor

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response. With respect to the use of a potentiostat comprising current-voltage converters, see Hashimoto, col. 5, ll. 40-58 and col. 15, l. 35 - col. 17, l. 7, especially col. 16, ll. 6-12 identifying the current to voltage conversion.

32. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '151 in view of any of Leader, Pfab, or DE '735 as applied to claim 30 above, and further in view of Heller (USP 6,017,696).

33. The references set forth all the limitations of the claim, but did not explicitly recite the use of labeling the analyte. Heller teaches that a dye (a labeling substance) can be affixed to the analyte such that the presence of the analyte can be detected optically at the electrode surface. See fig. 12b-12d and col. 23, l. 65 - col. 24, l. 18. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a labeling substance such that the presence of the analyte can be additionally detected optically.

#### *Allowable Subject Matter*

34. Claims 18 and 21-29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

35. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not disclose nor render obvious all the cumulative limitations of claims 1 and 18 with particular attention to having the step of separating the composite essentially perpendicularly to the longitudinal direction of the electrode material by cutting, sawing or by means of a separating disk or by taking apart the stacked plate-type insulating material.

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Although electrodes such as JP 04-223,257 ("JP '257") and EP 0 266 432 ("EP '432") teach the use of electrode constructions similar to that of the present invention, there is no obvious reason for utilizing either of these electrode constructions for the electrode of WO '151 as JP '257 and EP '432 are drawn to the construction of a single enzyme electrode in contrast to WO '151 that is drawn to a multi-component hybridization detection probe.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/

Primary Examiner, Art Unit 1795

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